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TESTA, HURWITZ & THIBEAULT, LLP HIGH STREET TOWER 125 HIGH STREET BOSTON, MA 02110			MAHATAN, CHANNING	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/072,634

Applicant(s)

STEITZ ET AL.

Examiner

Channing S Mahatan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-106 is/are pending in the application.
- 4a) Of the above claim(s) 63-106 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-63 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-106 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8 Sheets</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Restriction/Election Requirement

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- I. Claims 1-62, drawn to a computer system, molecular model, and method of identifying a lead candidate, classified in class 702, subclass 19.
- II. Claims 63-98, drawn to a computer system, and a method of identifying a lead candidate, classified in class 702, subclass 19.
- III. Claims 99-103, drawn to a protein synthesis inhibitor comprising a first and second binding domain, classified in class 536, subclass 6.5.
- IV. Claims 104 and 105, drawn to a protein synthesis inhibitor comprising a binding domain and an effector domain, classified in class 536, subclass 6.5.
- V. Claim 106, drawn to a protein synthesis inhibitor capable of contacting residues in Table 11A that define an anisomycin binding pocket of a large ribosomal subunit, classified in class 536, subclass 6.5.
- VI. Claim 106, drawn to a protein synthesis inhibitor capable of contacting residues in Table 12A that define a blasticidin binding pocket of a large ribosomal subunit, classified in class 536, subclass 6.5.
- VII. Claim 106, drawn to a protein synthesis inhibitor capable of contacting residues in Table 13A that define a carbomycin A binding pocket of a large ribosomal subunit, classified in class 536, subclass 7.1.

- VIII. Claim 106, drawn to a protein synthesis inhibitor capable of contacting residues in Table 14A that define a tylosin binding pocket of a large ribosomal subunit, classified in class 536, subclass 6.5.
- IX. Claim 106, drawn to a protein synthesis inhibitor capable of contacting residues in Table 15A that define a sparsomycin binding pocket of a large ribosomal subunit, classified in class 536, subclass 27.2.
- X. Claim 106, drawn to a protein synthesis inhibitor capable of contacting residues in Table 16A that define a virginiamycin binding pocket of a large ribosomal subunit, classified in class 536, subclass 6.5.
- XI. Claim 106, drawn to a protein synthesis inhibitor capable of contacting residues in Table 17A that define a spiramycin binding pocket of a large ribosomal subunit, classified in class 536, subclass 7.1.
- XII. Claim 106, drawn to a protein synthesis inhibitor capable of contacting residues in Table 18A that define an erythromycin binding pocket of a large ribosomal subunit, classified in class 536, subclass 7.2.
- XIII. Claim 106, drawn to a protein synthesis inhibitor capable of contacting residues in Table 19A that define an azithromycin binding pocket of a large ribosomal subunit, classified in class 536, subclass 6.5.
- XIV. Claim 106, drawn to a protein synthesis inhibitor capable of contacting residues in Table 20A that define a linezolid binding pocket of a large ribosomal subunit, classified in class 536, subclass 6.5.

The inventions are distinct, each from the other because:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04, M.P.E.P. § 808.01). In the instant case the different inventions are directed to methods and computer systems having different functions, different effects, and different modes of operation. For example, the method, molecular model, and computer system of Group I provides the limitation of a “molecular model of a ribofunctional locus of a large subunit of a ribosome” whereas the method and computer system of Group II provides the limitation of a “molecular model of at least a portion of a protein synthesis inhibitor”. Thus, Groups I and II have different functions, different effects, and different modes of operation.

Inventions I and III-XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04, M.P.E.P. § 808.01). In the instant case the different inventions wherein Group I is directed to a method, molecular model, computer system for identifying a candidate molecule utilizing a molecular model of a ribofunctional locus of a large subunit of a ribosome and Groups III-XIV are directed to protein synthesis inhibitors. Thus, Groups I and III-XIV have different functions, different effects, and different modes of operation.

Inventions II and III-XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the

product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case each of the protein synthesis inhibitors of Groups III-XIV may be used in the method and computer system of identifying a lead candidate of Group II, wherein the method and computer system can use the protein synthesis inhibitors as a “molecular model”. Further, the inventions of Groups III-XIV are directed to different products having different structural and functional characteristics, wherein the each of the protein synthesis inhibitors possess either a first and second binding domain or a first and effector domain or is capable of contacting residues found in Tables 11A-20A.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art because of their recognized divergent subject matter, and the search for each Group would require a non-coextensive non-patent literature search (i.e. the search required for Group I is not required for Group II), restriction for examination purposes as indicated is proper.

The Examiner has required restriction between product and process claims. Where Applicants elect claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of M.P.E.P. § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 C.F.R. § 1.116; amendments submitted after allowance are governed by 37 C.F.R. § 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. § 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. § 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See “Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b),” 1184 O.G. 86 (March 26, 1996).

Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicants are advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. § 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See M.P.E.P. § 804.01.

Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143).

TELEPHONE ELECTION

During a telephone conversation with Duncan Greenhaugh, via Michael Nesler, on 30 January 2004 a provisional election was made with traverse to prosecute the invention of Group I

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(claims 1-62; drawn to a computer system, molecular model, and method of identifying a lead candidate). Affirmation of this election must be made by Applicants in replying to this Office action. Claims 63-106 are withdrawn from further consideration by the Examiner, 37 C.F.R. 1.142(b), as being drawn to a non-elected invention.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 1-62.

INFORMATION DISCLOSURE STATEMENT

The reference (C88) to EP International Search Report (EP 01 30 6825.9) was lined through because the reference is not publicly available.

TITLE NOT DESCRIPTIVE

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The present title is directed to ribosomes and protein synthesis inhibitors whereas in contrast the elected claims are directed to a method, molecular model, and method of identifying a lead candidate utilizing a molecular model of a ribofunctional locus of a large ribosomal subunit.

Obviousness Double-Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 U.S.P.Q.2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 U.S.P.Q. 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

F.2d 937, 214 U.S.P.Q. 761 (C.C.P.A. 1982); *In re Vogel*, 422 F.2d 438, 164 U.S.P.Q. 619 (C.C.P.A. 1970); and, *In re Thorington*, 418 F.2d 528, 163 U.S.P.Q. 644 (C.C.P.A. 1969).

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. § 3.73(b).

Claims 33-62 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 76, and 79-105 of copending Application No. 09/922,251. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 33-62 of the instant application encompasses the same method of identifying a candidate molecule. For instance, both applications claim methods comprising the steps of “(a) providing a molecular model of a ribofunctional locus of a large subunit of a ribosome, wherein the molecular model is defined by atoms derived from an electron density map having a resolution of at least about 4.5Å; and (b) using the model to identify a candidate molecule having a surface complementary to the ribofunctional locus” or “(b) using the model to identify a candidate molecule capable of having binding specificity for the ribofunctional locus” (Application No. 09/922,251). It should be noted the limitations “having a surface complementary” and “capable of having binding specificity” are indistinguishable from one another, since it is unclear as to what is meant by the

limitation “complementary” (refer to below 35 U.S.C. § 112 2nd Paragraph rejection) or “binding specificity”. Thus, the aforementioned claims in the pending applications all maintain obvious embodiments, wherein the above limitations are considered overlapping.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims Rejected Under 35 U.S.C. § 101

35 U.S.C. § 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 32, 33, 34, 36, 37, and 41-62 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter.

NON-STATUTORY SUBJECT MATTER

Claims 32, 33, 34, 36, 37, and 41-62 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. The claimed invention is directed to a “molecular model”(i.e. data; claim 32) and a “method of identifying a candidate molecule”.

M.P.E.P. section entitled “Nonfunctional Descriptive Material” states:

Descriptive material that cannot exhibit any functional interrelationship with the way in which computing processes are performed does not constitute a statutory process, machine, manufacture or composition of matter and should be rejected under 35 U.S.C. 101. Thus, Office personnel should consider the claimed invention as a whole to determine whether the necessary functional interrelationship is provided.

Where certain types of descriptive material, such as music, literature, art, photographs and mere arrangements or compilations of facts or data, are merely stored so as to be read or outputted by a computer without creating any functional interrelationship, either as part of the stored data or as part of the computing processes performed by the computer, then such descriptive material alone does not impart functionality either to the data as so structured, or to the computer. Such “descriptive material” is not a process, machine, manufacture or composition of matter. (Data consists of facts, which become information when they are seen in context and convey meaning to people. Computers process data without any understanding of what that data represents. Computer Dictionary 210 (Microsoft Press, 2d ed. 1994).)

The policy that precludes the patenting of nonfunctional descriptive material would be easily frustrated if the same descriptive material could be patented when claimed as an article of manufacture. For example, music is commonly sold to consumers in the format of a compact disc. In such cases, the known compact disc acts as nothing more than a carrier for nonfunctional descriptive material. The purely nonfunctional descriptive material cannot alone provide the practical application for the manufacture.

Office personnel should be prudent in applying the foregoing guidance. Nonfunctional descriptive material may be claimed in combination with other functional descriptive multi-media material on a computer-readable medium to provide the necessary functional and structural interrelationship to satisfy the requirements of 35 U.S.C. 101. The presence of the claimed nonfunctional descriptive material is not necessarily determinative of nonstatutory subject matter. For example, a computer that recognizes a particular grouping of musical notes read from memory and upon recognizing that particular sequence, causes another defined series of notes to be played, defines a functional interrelationship among that data and the computing processes performed when utilizing that data, and as such is statutory because it implements a statutory process.

M.P.E.P. section entitled “Nonstatutory Subject Matter” (pages 2100-12, Columns 1-2) states:

Claims to processes that do nothing more than solve mathematical problems or manipulate abstract ideas or concepts are more complex to analyze and are addressed below.

If the “acts” of a claimed process manipulate only numbers, abstract concepts or ideas, or signals representing any of the foregoing, the acts are not being applied to appropriate subject matter. *Schrader*, 22 F.3d at 294-95, 30 U.S.P.Q.2d at 1458-59. Thus, a process consisting solely of mathematical operations, i.e., converting one set of numbers into another set of numbers, does not manipulate appropriate subject matter and thus cannot constitute a statutory process.

Further, M.P.E.P. section entitled “Statutory Process Claims” (page 2100-15, Column 1-2) states:

A claim that requires one or more acts to be performed defines a process. However, not all processes are statutory under 35 U.S.C. 101. *Schrader*, 22 F.3d at 296, 30 U.S.P.Q.2d at 1460. To be statutory, a claimed computer-related process must either: (A) result in a physical transformation outside the computer for which a practical application in the technological arts is either disclosed in the specification or would have been known to a skilled artisan (discussed in i) below), or (B) be limited to a practical application within the technological arts (discussed in ii) below). See *Diamond v. Diehr*, 450 U.S. at 183-84, 209 U.S.P.Q. at 6 (quoting *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1877)) (“A [statutory] process is a mode of treatment of certain materials to produce a given result. It is an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing.... The process requires that certain things should be done with certain substances, and in a certain order; but the tools to be used in doing this may be of secondary consequence.”). See also *Alappat*, 33 F.3d at 1543, 31 U.S.P.Q.2d at 1556-57 (quoting *Diamond v. Diehr*, 450 U.S. at 192, 209 U.S.P.Q. at 10). See also *id.* at 1569, 31 U.S.P.Q.2d at 1578-79 (Newman, J., concurring) (“unpatentability of the principle does not defeat patentability of its practical applications”) (citing *O’Reilly v. Morse*, 56 U.S. (15 How.) at 114-19). If a physical transformation occurs outside the computer, a disclosure that permits a skilled artisan to practice the claimed invention, i.e., to put it to a practical use, is sufficient. On the other hand, it is necessary for the claimed invention taken as a whole to produce a practical application if there is only a transformation of signals or data inside a computer or if a process merely manipulates concepts or converts one set of numbers into another.

The “molecular model” of claim 32 is interpreted to be data (i.e. non-functional descriptive material). The computer produces said “molecular model” (data) without any understanding of what the data represents, wherein the “purely non-functional descriptive material cannot alone provide the practical application for the manufacture”, and is thus non-statutory. The computational steps/processes of claims 33, 34, 36, 37, 41-62 are “mental” processes of performing mathematical operations (manipulation of numbers) applied to a computer. For example, instant claim 33 comprises the steps of providing a molecular model and using the model to identify a candidate molecule having a surface complementary to the ribofunctional locus. Simply identifying a molecule that is complementary to the ribofunctional locus provides no useful information; since there is no further indication (i.e. steps) what the complementary molecule identified means or is useful for. Further, claims 36 and 37 (additional steps of determination and/or identification) are considered non-biological processes that are performed within a computer. The claims do not recite any concrete or tangible results; therefore the claims do not recite statutory subject matter.

Claims Rejected Under 35 U.S.C. § 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 U.S.P.Q. 546 (B.P.A.I. 1986) and reiterated by the Court of Appeals in In re Wands, 8 U.S.P.Q.2d 1400 at 1404 (C.A.F.C. 1988). The factors to be considered in determining whether undue experimentation is required

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include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

LACK OF ENABLEMENT

Claims 3, 7, 21, 22, 58, and 59 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 3, 7, 21, 22, 58, and 59 are directed to atomic coordinates deposited at the Research Collaboratory for Structural Bioinformatics Protein Data Bank with accession numbers PDB ID: 1FFK, 1FFZ, 1FG0, etc. and the specification makes reference to PDB accession (beginning on page 15, lines 12-13; page 27, line 8). The Protein Data Bank information is considered incorporation of essential material in the disclosure. This is an improper incorporation of essential material as it is not from a patent or allowed application. Furthermore, atomic coordinate information is continuously updated it is not clear what information is intended. The absence of the deposited coordinates in the original disclosure thus fails to enable one of skill in the art proper guidance to make and/or use the claimed computer system and method.

Claims Rejected Under 35 U.S.C. § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-7 and 33-62 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

VAGUE AND INDEFINITE

Claims 5-7 are confusing wherein the claims are dependent upon each other and are thus confusing. Clarification of the claim language is requested.

Claim 33 and all claims dependent therefrom recite the limitation “complementary to the ribofunctional locus” which is considered vague and indefinite. It is unclear what is meant by said limitation. A possible interpretation is that “complementary” to the ribofunctional locus is meant to be exact or to include those with less than 100% complementarity, such as 90%, 50%, or even 10%. Clarification of the metes and bounds, via clearer claim language, is requested.

Claim 37 and all claims dependent therefrom recites the phrase “modified molecule” which is vague and indefinite. It is unclear what limitations are provided for by a “modified molecule”. For example, identification of a “modified molecule” would require at least a reference point/molecule that can be utilized to compare a molecule and identify it as modified. Clarification of the metes and bounds, via clearer claim language, is requested.

Claim 40 is confusing wherein the instant claim recites “the additional step of producing the modified molecule”, however; claim 38 (which claim 40 via 39 depends from) recites the same step. Clarification of the claim(s) language and format is requested.

Claim 41 and 42 recites the phrase “antibiotic analogue” which is vague and indefinite. It is unclear what defines an antibiotic analogue (what limitations are provided for by analogue?). Clarification of the metes and bounds, via clearer claim language, is requested.

Claims Rejected Under 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-31 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Brunger et al. (Crystallography & NMR System: A new software Suite for Macromolecular Structure Determination, Acta Crystallographica. 01 September 2000, Volume D54, Part 9, pages 905-921).

The following excerpt is from M.P.E.P. § 2106 Section VI “DETERMINE WHETHER THE CLAIMED INVENTION COMPLIES WITH 35 U.S.C. § 102 AND 103” (particular emphasis on bolded areas) and is applied to the below 35 U.S.C. § 103 rejection, wherein the “data indicative of atomic co-ordinates derived from an electron density map having a resolution of at least about 4.5 Å and defining a ribofunctional locus of a large subunit of a ribosome”; 2) three-dimensional model representative of the ribofunctional locus” (claim 47; lines 2-4 and 6-7) is considered “non-functional descriptive” material (i.e. mere arrangement of data; failing to satisfy the practical application requirement). Further, examples are provided for in the M.P.E.P. regarding situations of nonfunctional descriptive material.

As is the case for inventions in any field of technology, assessment of a claimed computer-related invention for compliance with 35 U.S.C. 102 and 103 begins with a comparison of the claimed

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subject matter to what is known in the prior art. **If no differences are found between the claimed invention and the prior art, the claimed invention lacks novelty and is to be rejected by Office personnel under 35 U.S.C. 102.** Once distinctions are identified between the claimed invention and the prior art, those distinctions must be assessed and resolved in light of the knowledge possessed by a person of ordinary skill in the art. Against this backdrop, one must determine whether the invention would have been obvious at the time the invention was made. If not, the claimed invention satisfies 35 U.S.C. 103. Factors and considerations dictated by law governing 35 U.S.C. 103 apply without modification to computer-related inventions. Moreover, merely using a computer to automate a known process does not by itself impart nonobviousness to the invention. See *Dann v. Johnston*, 425 U.S. 219, 227-30, 189 USPQ 257, 261 (1976); *In re Venner*, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958).

If the difference between the prior art and the claimed invention is limited to descriptive material stored on or employed by a machine, Office personnel must determine whether the descriptive material is functional descriptive material or nonfunctional descriptive material, as described *supra* in paragraphs IV.B.1(a) and IV. B.1(b). Functional descriptive material is a limitation in the claim and must be considered and addressed in assessing patentability under 35 U.S.C. 103. Thus, a rejection of the claim as a whole under 35 U.S.C. 103 is inappropriate unless the functional descriptive material would have been suggested by the prior art. *In re Dembiczak*, 175 F.3d 994, 1000, 50 USPQ2d 1614, 1618 (Fed. Cir. 1999). **Nonfunctional descriptive material cannot render nonobvious an invention that would have otherwise been obvious. Cf. *In re Gulack*, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983) (when descriptive material is not functionally related to the substrate, the descriptive material will not distinguish the invention from the prior art in terms of patentability).** Common situations involving nonfunctional descriptive material are:

- a computer-readable storage medium that differs from the prior art solely with respect to nonfunctional descriptive material, such as music or a literary work, encoded on the medium,
- a computer that differs from the prior art solely with respect to nonfunctional descriptive material that cannot alter how the machine functions (i.e., the descriptive material does not reconfigure the computer), or
- a process that differs from the prior art only with respect to nonfunctional descriptive material that cannot alter how the process steps are to be performed to achieve the utility of the invention.

Thus, if the prior art suggests storing a song on a disk, merely choosing a particular song to store on the disk would be presumed to be well within the level of ordinary skill in the art at the time the invention was made. The difference between the prior art and the claimed invention is simply a rearrangement of nonfunctional descriptive material.

All limitations concerning the type of data are given no patentable weight as they are considered to be non-functional descriptive material. As such, the claim limitations are considered to be limited to a memory storing any data, a processor in communication with memory, and capable of generating a three-dimensional model.

Brunger et al. describe a software suite for macromolecular structure determination by X-ray crystallography or nuclear magnetic resonance spectroscopy (i.e. drug design), wherein the software allows users to perform operations on data structures (i.e. electron density maps, atomic properties, etc.) (page 905, column 1, lines 1-5). The authors indicate that the software has been tested on various computers with processors, memory, and graphical display (Figure 1; page 907, column 2, lines 13-16; and page 919, column 1, lines 27-40). Thus, Brunger et al. anticipates the claimed invention wherein the cited reference teaches a computer system having 1) memory; 2) processor in electrical communication with the memory; 3) a program for generating a three-dimensional model; 4) a device for providing a visual representation; 5) a program for performing drug design; and 6) a molecular model.

OBJECTION TO DISCLOSURE

The disclosure is objected to because of the following informalities:

The disclosure is objected to because it contains embedded hyperlinks and/or other form of browser-executable code (i.e. page 33, line 2; page 37, line 10; page 41, line 3, etc.).

Applicants are requested to delete the embedded hyperlinks and/or other form of browser-executable code. Applicants are requested to review the application for embedded hyperlinks and/or other forms of browser-executable code and delete them. Embedded hyperlinks and/or other form of browser-executable code are impermissible in the text of the application as they represent an improper incorporation by reference. See M.P.E.P. § 608.01 and 608.01(p).

Appropriate Correction Is Requested.

No Claims Are Allowed.

Art Unit: 1631

EXAMINER INFORMATION


Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Channing S. Mahatan whose telephone number is (571) 272-0717. The Examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina M. Plunkett, whose telephone number is (571) 272-0549 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date: February 20, 2004
Examiner Initials: CS01


MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

2.23.04